

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Cheryl Fitzer-Attas et al.

Application No.: 10/619,454

Confirmation No.: 7700

Filed: July 16, 2003

Art Unit: 1649

For: PEPTIDES AND METHODS OF  
SCREENING IMMUNOGENIC PEPTIDE  
VACCINES AGAINST ALZHEIMER'S  
DISEASE

Examiner: S. H. Standley

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:  
(Check one of the boxes A-D)

- ☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))

☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☒ A. Pursuant to the 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the U.S. **Patent(s) and/or U.S. Patent Application Publication(s)** on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

<<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

- ☐ 3. Cite No(s). \_\_\_\_\_ are not in the English language.  
In accordance with 1.98(c), Applicant states:
- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.
- ☐ A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

- ☒ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).
- ☒ 5. Other information being provided for the examiner's consideration follows:

An International Search Report, dated September 27, 2006, which issued during the prosecution of International Application No. PCT/US03/22280 which corresponds to the present application.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: December 8, 2006

Respectfully submitted,

By  MARIE LOLAITO  
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Registration No.: 46,550

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Attorneys/Agents For Applicant

Substitute for form 1449/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>		<b>Complete If Known</b> Application Number: 10/619,454-Conf. #7700 Filing Date: July 16, 2003 First Named Inventor: Cheryl Fitzer-Altas Art Unit: 1649 Examiner Name: S. H. Standley Attorney Docket Number: 20555/1203432-US1	
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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number/Kind Code <sup>2</sup> (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-4,582,788	04-15-1985	Ertlich	
	AB*	US-4,683,202-B1	07/1987	Mullis	
	AC*	US-2004/0043935-A1	03-04-2004	Frangione et al.	
	AD*	US-2003/0166558-A1	09-04-2003	Frangione et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> /Number/Kind Code <sup>3</sup> (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	BA	WO-99/27944	06-10-1999	Athena Neurosciences Inc et al.	
	BB	WO-00/72876	12-07-2000	Neuralab Ltd et al.	
	BC	WO-01/019182	11-29-2001	Univ New York et al.	
	BD	WO-03/045128	06-05-2003	Univ New York et al.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 606. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 601.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume- issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Bauer, J. et al. "Inflammation in the nervous system: the human perspective". 2001 <i>Glia</i> 36: 235-243.		
	CB	Blen, C.G., et al. "Destruction of neurons by cytotoxic T cells: a new pathogenic mechanism in Rasmussen's encephalitis." <i>Ann Neurol</i> 2002 March; 51(3):311-8		
	CC	Blasko I, et al., "B TNFalpha plus IFNgamma induce the production of Alzheimer beta-amyloid peptides and decrease the secretion of APPs." <i>FASEB J</i> 1999 January; 13(1):83-8		
	CD	Busciglio, J. et al. "Generation of beta-amyloid in the secretory pathway in neuronal and nonneuronal cells." (1993) <i>Proc Natl Acad Sci USA</i> 90:2092-2096		
	CE	Buus S, et al., "Receptor-ligand interactions measured by an improved spun column chromatography technique. A high efficiency and high throughput size separation method." <i>Biochim Biophys Acta</i> . Apr. 13, 1995; 1243(3):453-60.		
	CF	Check, E. "Nerve inflammation halts trial for Alzheimer's drug." <i>Nature</i> . Jan. 31, 2002;415(8871):482.		
	CG	Gay, F. W. et al. "The application of multifactorial cluster analysis in the staging of plaques in early multiple sclerosis. Identification and characterization of the primary demyelinating lesion."		

Examiner Signature	Date Considered
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Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/619,454-Conf. #7700
		Filing Date	July 16, 2003
		First Named Inventor	Cheryl Fitzer-Attas
		Art Unit	1649
		Examiner Name	S. H. Standley
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		Attorney Docket Number	20555/1203432-US1

		Brain. 1997 August;120 (Pt 8):1461-83.	
CH	Geddes, J. W. et al. "N-terminus truncated beta-amyloid peptides and C-terminus truncated secreted forms of amyloid precursor protein: distinct roles in the pathogenesis of Alzheimer's disease." <i>Neurobiol Aging</i> . 1999 20(1):75-9		
CI	Glennner, G. G. and Wong, C. W. "Alzheimer's disease: initial report of the purification and characterization of a novel cerebrovascular amyloid protein." (1984) <i>Biochem Biophys Res Commun</i> 120:885-890.		
CJ	Griffin D E, et al. "The immune response in viral encephalitis." <i>Semin Immunol</i> 1992 April; 4(2):111-9.		
CK	Haass, C. et al. "Amyloid beta-peptide is produced by cultured cells during normal metabolism." (1992) <i>Nature</i> 359:322-325		
CL	Haas, C. et al. "Mutations associated with a locus for familial Alzheimer's disease result in alternative processing of amyloid b-protein precursor." <i>J Biol. Chem.</i> 268, 17741-17748.		
CM	Higgins, L.S. et al. "p3 b amyloid peptide has a unique and potentially pathogenic immunohistochemical profile in Alzheimer's disease brain." <i>Am J. Pathol</i> 149, 585-598.		
CN	Janus, C. et al. "A beta peptide immunization reduces behavioural impairment and plaques in a model of Alzheimer's disease." 2000 <i>Nature</i> 408, 979-982.		
CO	Joachim, C. L. et al. "Protein chemical and immunocytochemical studies of meningovascular beta-amyloid protein in Alzheimer's disease and normal aging." (1988) <i>Brain Res</i> 474:100-111		
CP	Kang, J. et al. "The precursor of Alzheimer's disease amyloid A4 protein resembles a cell-surface receptor." <i>Nature</i> . Feb. 19-25, 1987; 325(6108):733-6		
CQ	Kimura, T. & Griffin, D. E., "The role of CD8(+) T cells and major histocompatibility complex class I expression in the central nervous system of mice infected with neuroinfective Sindbis virus." <i>J Virol</i> 2000 July; 74(13):6117-25		
CR	Lalowski M et al., "The "nonamyloidogenic" p3 fragment (amyloid beta17-42) is a major constituent of Down's syndrome cerebellar preamyloid." 1996 <i>J Biol Chem</i> 271(52):33923-31		
CS	Lamer, A. J. "Hypothesis: amyloid b peptides truncated at the N-terminus contribute to the pathogenesis of Alzheimer's disease." <i>Neurobiol. Of Aging</i> 20, 65-69.		
CT	Marx, F., "Transfected human B cells: a new model to study the functional and immunostimulatory consequences of APP production." <i>Exp Gerontol</i> 1999 September; 34(5):783-95		
CJ	Morgan, D., et al. "A beta peptide vaccination prevents memory loss in an animal model of Alzheimer's disease." 2000 <i>Nature</i> 408, 982-985.		
CV	Mori, H. et al. "Mass spectrometry of purified amyloid beta protein in Alzheimer's disease." (1992) <i>J Biol Chem</i> 267:17062-17066.		
CW	Naslund, J. et al. "Relative abundance of Alzheimer A beta amyloid peptide variants in Alzheimer disease and normal aging." (1994) <i>Proc Natl Acad Sci USA</i> 91:8378-8382.		
CX	Neumann, H. et al. "Major histocompatibility complex (MIC) class I gene expression in single neurons of the central nervous system: differential regulation by interferon (IFN)-gamma and tumor necrosis factor (TNF)-alpha." 1997 <i>J Exp Med</i> 185: 305-316.		

Examiner Signature	Date Considered
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Substitution for form 1449/PTO  <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; margin: 5px 0;">(Use as many sheets as necessary)</p>				<b>Complete if Known</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;">Application Number</td> <td>10/619,454-Conf. #7700</td> </tr> <tr> <td>Filing Date</td> <td>July 16, 2003</td> </tr> <tr> <td>First Named Inventor</td> <td>Cheryl Fitzer-Altas</td> </tr> <tr> <td>Art Unit</td> <td>1649</td> </tr> <tr> <td>Examiner Name</td> <td>S. H. Standley</td> </tr> <tr> <td>Attorney Docket Number</td> <td>20555/1203432-US1</td> </tr> </table>		Application Number	10/619,454-Conf. #7700	Filing Date	July 16, 2003	First Named Inventor	Cheryl Fitzer-Altas	Art Unit	1649	Examiner Name	S. H. Standley	Attorney Docket Number	20555/1203432-US1
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	CY	Oldstone, M. B. & Southern, P. J., "Trafficking of activated cytotoxic T lymphocytes into the central nervous system: use of a transgenic model." 1993 J Neuroimmunol 48:25-31	
	CZ	Ostergaard Pedersen L., et al, "Efficient assembly of recombinant major histocompatibility complex class I molecules with preformed disulfide bonds." Eur J. Immunol. 2001 October; 31(10):2986-96	
	CA1	Parker, K. C., et al, "Scheme for ranking potential HLA-A2 binding peptides based on independent binding of individual peptide side-chains." J. Immunol. 152:163.	
	CB1	Pike, C.J., et al, "Amino-terminal deletions enhance aggregation of P-amyloid peptides in vitro". J Biol Chem 270, 23895-8.	
	CC1	Prelli, F. et al. "Differences between vascular and plaque core amyloid in Alzheimer's disease." (1988) J Neurochem 51:648-651	
	CD1	Rammensee, Hans-Georg, et al. "SYFPEITHI: database for MHC ligands and peptide motifs." Immunogenetics (1999) 50: 213-218 (access via: <a href="http://www.uni-tuebingen.de/unifox/">http://www.uni-tuebingen.de/unifox/</a> )	
	CE1	Reche, P.A., et al. "Prediction of MHC Class I Binding Peptides Using Profile Motifs." Human Immunology 63, 701-709 (2002).	
	CF1	Roher, A. E., et al. "beta-Amyloid-(1-42) is a major component of cerebrovascular amyloid deposits: Implications for the pathology of Alzheimer disease." (1993) Proc Natl Acad Sci USA 90:10836-10840	
	CG1	Schenk, D. et al. "Immunization with amyloid-beta attenuates Alzheimer-disease-like pathology in the PDAPP mouse." 1999 Nature 400, 173-177.	
	CH1	Seubert, P. et al. "Isolation and quantification of soluble Alzheimer's beta-peptide from biological fluids." (1992) Nature 359:325-327	
	CI1	Stumolo, T., et al., "Generation of tissue-specific and promiscuous HLA ligand database using DNA microarrays and virtual HLA class II matrices." Nat. Biotechnol. 17, 555-561(1999)	
	CJ1	Tekiran, T. L., "Commentary: Abeta N-Terminal isoforms: Critical contributors in the course of AD pathophysiology." J Alzheimers Dis. 2001 April; 3(2):241-248.	
	CK1	Traugott, U. "Multiple sclerosis: relevance of class I and class II MHC-expressing cells to lesion development." 1987 J Neuroimmunol 16: 283-302.	
	CL1	Vass, K. & Laessmann, H. "Intrathecal application of interferon gamma. Progressive appearance of MHC antigens within the rat nervous system." 1990 Am J. Pathol 137: 789-800.	
	CM1	Scharf et al., "Direct Cloning and Sequence Analysis of Enzymatically Amplified Genomic Sequences." Science, Vol. 233, No. 4768, pp. 1076-1078	
	CN1	Cox et al., "HLA-DR Typing "at the DNA Level": RFLPs and Subtypes Detected with a DRB cDNA Probe." Am. J. Hum. Gen., 43:954-963, 1988	
	CO1	Tiercy, Jean-Marie, et al., "Identification and Distribution of Three Serologically Undetected Alleles of HLA-DR by Oligonucleotide-DNA Typing Analysis." Proc. Natl. Acad. Sci. USA, Vol. 85, pp. 198-202, 1988	
	CP1	Tiercy, Jean-Marie, et al., "DNA Typing of DRB6 Subtypes: Correlation with DRB1 and DRB3 Allelic Sequences by Hybridization with Oligonucleotide Probes." Hum. Immunol. 24, pp. 1-14 (1989)	
	CQ1	Salik, Randall K., et al., "Analysis of Enzymatically Amplified beta-globin and HLA-DQA DNA with	

Examiner Signature	Date Considered
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Substitute for form 1445PPTO  <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; margin: 5px 0;">(Use as many sheets as necessary)</p>				<b>Complete if Known</b>	
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Art Unit				1649	
Examiner Name				S. H. Standley	
Attorney Docket Number				20555/1203432-US1	
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		Allele-Specific Oligonucleotide Probes." Nature, Vol. 324, pp. 163-166, 1996	
	CR1	Bugawan, Theodorica L., et al., "Analysis of HLA-DP Allelic Sequence Polymorphism Using the In Vitro Enzymatic NDA Amplification of DP- $\alpha$ and DP- $\beta$ Loci." J. Immunol., Vol. 141, No. 12, pp. 4024-4030, 1988	
	CS1	Gyllenstein, Ulf B., et al., "Generation of Single-Stranded DNA by the Polymerase Chain Reaction and its Application to Direct Sequencing of the HLA-DQA Locus." Proc. Natl. Acad. Sci. USA, Vol. 85, pp. 7652-7656, 1988	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached

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